

## **REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the reasons which follow.

Claims 1, 10, 11, and 19-24 are pending. Claims 2-6, 8-9, and 13-18, drawn to non-elected claims, are withdrawn from consideration. Applicant reserves the right to file one or more divisional application(s) on the subject matter of the non-elected claims. Method claim 16, drawn to a non-elected invention, remains withdrawn from further consideration. Applicant respectfully requests the rejoinder of this method claim pursuant to the *Ochiai/Brouwer* guidelines.

A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, are presented, with an appropriate defined status identifier.

### ***Rejection Under 35 U.S.C. § 112, First Paragraph***

The Examiner considers claims 1, 10-11, and 19-24, as indefinite because the molecular weight (MW) of the claimed BLCA-6 protein remains unclear. The Examiner based this rejection on the following grounds, namely: (i) the inventor's declaration filed April 14, 2003, did not indicate that the BLCA-6 protein in the specification is the same as that in the cited reference (Getzenberg *et al.*, 1996); (ii) the photograph of the 2-D gel in the preprint is unclear; and (iii) instead of stating that the MW is 31-kDa, Applicant's response filed April 14, 2003 stated that the "claimed antibody specifically binds to the BLCA-6 protein having a much lower molecular weight (about 22-kDa)."

In response, Applicant submits that the correct molecular weight of the claimed BLCA-6 protein is about 31-kDa. In the accompanying unexecuted Supplemental Declaration, Applicant states that the BLCA-6 protein in the specification is the same as that of Getzenberg *et al.*, 1996. Applicant will submit an executed copy of the Supplemental Declaration in a supplemental response within two weeks of the submission of this Reply.

In addition, Applicant encloses a new photograph of a 2-D gel showing that the MW of BLCA-6 protein is above the 29 kDa molecular weight marker and, therefore, the MW is

indeed about 31-kDa, and not 22-kDa. Applicant also submits that the information pertaining to the MW of the claimed protein submitted in the April 14<sup>th</sup> response is an inadvertent error. The correct MW in the enclosed parenthesis should be 31-kDa and not 22-kDa.

As explained in the previous response, Applicant has inadvertently disclosed the incorrect MW of the claimed protein during the preparation of the provisional and parent applications, U.S.S.N. 60/006,226 and 08/742,850, filed 11/03/1995 and 11/01/1996 (now U.S. Patent No. 5,866,535).

At the outset, Applicant would like to explain (a) how the incorrect 22-kDa protein was introduced into the preprint of the Getzenberg *et al.* (1996) reference and how this error was discovered and eventually corrected during the publication phase of the reference and (b) how this error was introduced into the preparation of the above-mentioned provisional and parent applications.

During the submission of the preprint, Applicant received a communication dated December 20, 1995, from the Managing Editor of the Cancer Research journal, enclosing comments from two reviewers (see Appendix A). On page 1 of the Dec. 20<sup>th</sup> letter, Reviewer #1 inquired about the MW discrepancy of the BLCA-6 protein in Table 2 and Figures 1, 2B and 2C. In a letter dated January 3, 1996, Applicant clarified this error by stating that the correct MW of BLCA-6 protein in Table 2 was indeed 31-kDa (see Appendix B). Unfortunately, this discrepancy was only discovered more than a month after the filing of the provisional application but was never corrected in the provisional and parent applications or communicated to the office of the undersigned.

As previously explained, Applicant submitted the preprint of the cited reference to his undersigned attorney at Foley & Lardner, as an invention disclosure in the filing of the provisional application. This preprint was received and stamped on October 18, 1995. As indicated at page 20, Table 2 of the preprint, the molecular weight of BLCA-6 protein was 22-kD. However, at page 21, Figure 1B, a silver stained 2-D electrophoresis gel depicted a BLCA-6 protein that was above the 29 kD molecular weight marker protein. This error was never corrected and the same error is found in the parent application.

Nevertheless, Applicant would like to stress that correct molecular weight and pI of the claimed human BLCA-6 protein is about 31-kD and 8.0 respectively, and that the correct molecular weight is an inherent property of this protein. One of ordinary skill in the art, upon following the procedural steps for collecting the samples and performing the protein separation described in the application as filed, would inherently obtain a protein having a molecular weight and pI equal to about 31-kD and 8.0, respectively. In fact, Applicant has repeated this procedure following the disclosure in the specification and has obtained a protein having a MW and pI of about 31-kD and 8.0, respectively. Accordingly, the 31-kD molecular weight and pI of 8.0 are both inherent properties of the BLCA-6 protein that result from the above-mentioned techniques. The inherent properties were shown in Figure 1B of the preprint and disclosed in the Getzenberg *et al.*, *Cancer Research* **56**:1690-94, 1996. As an additional evidence, Applicant encloses a clearer photograph of a 2-D gel showing the correct MW and pI of the claimed BLCA-6 protein (see Appendix C).

In light of the above remarks, Applicant earnestly requests the reconsideration and withdrawal of this rejection.

***Rejection Under 35 U.S.C. § 112, First Paragraph***

According to the Examiner, claims 1, 10-11, and 19-24 are non-enabling because the “specification does not describe the invention to enable one skill[ed] in the art to make and use the invention.

As mentioned above, the claimed BLCA-6 protein, having a sequence of SEQ ID NO:4, has a true MW and pI of about 31-kDa and 8.0, respectively. The disclosure of the 22-kDa protein is an inadvertent error made due to the above-mentioned circumstances. This inherent property is supported by the originally filed specification and should not constitute new matter.

As previously explained in the April 14<sup>th</sup> response, the case law holds that introduction of an inherent property (such as the correct chemical structure of a substance made in a working example of the specification) is not new matter. The rejection offers no authority to the contrary.

In the present case, the specification supports and teaches the scope of claims 1, 10-11, and 19-24. The claimed BLCA-6 protein necessarily and inherently possesses a molecular weight of 31-kD and pI of 8.0. Therefore, despite the incorrect recitation of the MW, one of ordinary skill in the art would inherently obtain a protein of about 31-kD and pI of 8.0.

In light of the foregoing amendments and remarks, Applicant respectfully requests the Examiner to reconsider and withdraw the rejections.

***Priority***

The Examiner has granted the instant application a priority date of May 30, 2001 on the basis of his consideration that the specification contains new matter and that the pending claims are non-enabling. Applicant respectfully disagrees with the Examiner on this issue.

Based on the inherent property of the BLCA-6 protein and the above-mentioned arguments, Applicant requests the Examiner to reconsider the priority date of the present application as November 3, 1995.

***Rejection Under 35 U.S.C. § 102***

The Examiner rejects claims 1, 10-11, 20 and 24 as being anticipated by Getzenberg *et al.* (1996). In particular, the Examiner alleges that Getzenberg *et al.* (1996) teach (i) nuclear matrix proteins which are present in bladder cancer cells and not in normal bladder cells; and (ii) that these proteins have been isolated and are being used to raise antibodies to the proteins. In addition, the protein of Getzenberg *et al.* (1996) is not elevated in patients with cystitis and has the sequence of SEQ ID NO:4.

Applicant submits that Getzenberg *et al.* (1996) is not a patent-defeating reference because it is Applicant's own publication and has an effective prior art date of April 1996, which is after the effective priority date of the present application, that is, November 3, 1995.

Therefore, in light of the early conception date of the present invention and the above-mentioned remarks, Applicant respectfully requests the Examiner to reconsider and withdraw this rejection.

***Rejection Under 35 U.S.C. § 103***

The Examiner also rejects the claims 1, 10-11, and 19-24, as being unpatentable over Getzenberg *et al.* (1996), as applied to claims 1, 10-11, 20 and 24, and further in view of Coffey *et al.* (U.S. Patent No. 6,030,793). The Examiner acknowledges that Getzenberg *et al.* (1996) “does not exemplify the production of the antibody or a fragment or a label and relies on Coffey *et al.* on the teaching of antibodies to NMP and the labeling of the antibodies with a therapeutic or a radioisotope. Thus, the Examiner is heard to allege that it would have been obvious for one of the ordinary skill in the art to produce an antibody to the BLCA-6 protein of Getzenberg *et al.* for imaging or therapy, pursuant to Coffey *et al.* Applicant respectfully traverses this rejection.

As a primary reference, Getzenberg *et al.* (1996) is not combinable with Coffey *et al.* because it is not a patent-defeating reference for the reasons set forth above. Without the primary reference, Coffey *et al.* cannot cure the deficiencies that are absent in Getzenberg *et al.* Accordingly, there is no alleged case of prima facie obviousness, and as a result of these deficiencies, it is respectfully requested that the rejection under section 103 be withdrawn.

### CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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FOLEY & LARDNER  
Customer Number: 22428



22428

PATENT TRADEMARK OFFICE

Telephone: (202) 672-5569

Facsimile: (202) 672-5399

By Stephen B. Maebius

Stephen B. Maebius  
Attorney for Applicant  
Registration No. 35,264